REMARKS

Claims 38 through 58, 61, 64, 65, 66, 68, and 69 are pending in this application. Claims 38, 54, 55, and 57 have been amended herein. Support for the amendment to claim 38 may be found in Example I at pages 23-26 of the specification. Support for the amendments to claims 54, 55, and 57 may be found in the claims as filed originally, as well as at page 14, lines 6-26. Reconsideration of this application in view of the foregoing amendment and the following remarks is requested respectfully as well.

Rejections Withdrawn:

The Applicant appreciates the consideration of the remarks filed October 20, 2004, and withdrawal of the objections to the claims and the rejections under 35 U.S.C. § 112, first paragraph.

Response to Arguments:

The Applicant appreciates the consideration of the arguments filed October 20, 2004. The Office action acknowledges that Lanza is used for a different purpose than the claimed invention, but asserts that the purpose is not specified in the claims. Claim 38 has consequently been amended to recite "preparing the sample for analysis comprising the steps of fixation, processing, imbedding, deparaffinization, and dehydration, wherein ultrasound at a frequency of at least 100 kHz is applied during each step except imbedding," as well as reciting applying ultrasound at a frequency of at least 100 kHz to a sample during an analysis such as immunohistochemistry, in situ hybridization, fluorescent in situ hybridization, a Southern hybridization, a Northern hybridization, a Western annealing, or an ELISA.

Claim Rejections - 35 U.S.C. § 112:

Claim 38 was rejected under 35 U.S.C. § 112, second paragraph, as being incomplete for omitting essential steps. The rejection is traversed, to the extent it might apply to the claims as amended.

The Office action asserts that claim 38 omits essential steps, the omission amounting to a gap between steps, and cites M.P.E.P. § 2172.01.

M.P.E.P. § 2172.01, however, says only that,

"In addition, a claim which fails to interrelate essential elements of the invention

> as defined by applicant(s) in the specification may be rejected under 35 U.S.C. 112, second paragraph, for failure to point out and distinctly claim the invention. See In re Venezia, 530 F.2d 956, 189 USPQ 149 (CCPA 1976); In re Collier, 397 F.2d 1003, 158 USPQ 266 (CCPA 1968).

Here, the Office action has not asserted that claim 38 fails to interrelate elements *as defined by the applicant in the specification*, as required by M.P.E.P. § 2172.01, but only that it is unclear how the ultrasound is used, when it is used, what it is directed at. Even if that were so, it still wouldn't amount to indefiniteness since, as noted further in M.P.E.P. § 2172.01,

> But see Ex parte Nolden, 149 USPQ 378, 380 (Bd. Pat. App. 1965) ("[I]t is not essential to a patentable combination that there be interdependency between the elements of the claimed device or that all the elements operate concurrently toward the desired result"); Ex parte Huber, 148 USPQ 447, 448-49 (Bd. Pat. App. 1965) (A claim does not necessarily fail to comply with 35 U.S.C. 112, second paragraph where the various elements do not function simultaneously, are not directly functionally related, do not directly intercooperate, and/or serve independent purposes.)."

Since is not essential to a patentable combination that there be interdependency between the elements of the claimed device or that all the elements operate concurrently toward the desired result, the Applicant submits respectfully that claim 38 is definite. Still, in the interest of compact prosecution only, and not for any reason of patentability, the Applicant has amended claim 38 to make it more definite, in substantial accord with the Examiner's suggestion. The Applicant appreciates the Examiner's suggestion.

With respect to claims 50 and 52, claims 50 and 52 recite, inter alia "one head on a single transducer produces an intensity different from an intensity produced by a second head on said single transducer," and "each of said transducers produces an ultrasound intensity different from an ultrasound intensity produced by at least one other transducer." The specification describes applying both high intensity and low intensity ultrasound to tissue samples during, e.g., biological reactions, fixation, processing, embedding, deparaffinizing, and dehydration at page 10, lines 12-20, contrary to the assertion in the Office action.

Neither claim 50 nor claim 52 recites frequency, so it is not immediately clear to the Applicant why claims 50 and 52 appear to contradict any examples. The description of multiple heads and intensities at page 14, lines 6-26 is not limited to any particular process, but rather describes the benefits of multiple heads producing different intensities generally. It is thus

submitted that claims 50 and 52 are clearly supported by the specification.

Claims 54, 55, and 57 have been amended to make them more definite. Withdrawal of the rejection is earnestly solicited.

Claim Rejections - 35 U.S.C. § 102:

Claims 38, 39, 40, 43, 45-48, 56, and 58-64 were rejected under 35 U.S.C. § 102(b) as anticipated by Lanza et al., US 5,958,371. The rejection is traversed, to the extent it might apply to the claims as amended.

Claim 38 recites:

"preparing the sample for analysis comprising the steps of fixation, processing, imbedding, deparaffinization, and dehydration, wherein ultrasound at a frequency of at least 100 kHz is applied during each step except imbedding," as well as

"analyzing the prepared sample using a process selected from the group consisting of:

immunohistochemistry,

in situ hybridization,

fluorescent in situ hybridization,

a Southern hybridization,

a Northern hybridization,

a Western annealing, and

an ELISA; and

applying ultrasound at a frequency of at least 100 kHz to said sample during said analysis."

Lanza neither teaches, discloses, nor suggests either applying ultrasound at a frequency of at least 100 kHz during each step except imbedding while preparing a sample for analysis comprising the steps of fixation, processing, imbedding, deparaffinization, and dehydration at any frequency, let alone a frequency of at least 100 kHz, or applying ultrasound at a frequency of at least 100 kHz to a sample during an analysis such as immunohistochemistry, in situ hybridization, fluorescent in situ hybridization, a Southern hybridization, a Northern hybridization, a Western annealing, or an ELISA. Lanza makes no mention at all of performing hybridization on nitrocellulose membranes using ultrasound at column 7, lines 35-64, contrary to the assertion in the Office action. Rather, Lanza uses ultrasound for *detecting* any molecular

epitope or receptor . . . without the need for use of ionizing radiation with or without associated invasive procedures, as described at column 7, lines 43 through 45, not applying ultrasound at a frequency of at least 100 kHz during each step except imbedding while preparing a sample for analysis comprising the steps of fixation, processing, imbedding, deparaffinization and dehydration, or applying ultrasound at a frequency of at least 100 kHz to a sample during an analysis such as immunohistochemistry, in situ hybridization, fluorescent in situ hybridization, a Southern hybridization, a Northern hybridization, a Western annealing, or an ELISA, as recited in claim 38.

Furthermore, Lanza describes ultrasound-based ELISA-type laboratory diagnostic *assays* in liquid and solid phase systems at column 7, lines 55-60, not applying ultrasound at a frequency of at least 100 kHz during each step except imbedding while preparing a sample for analysis comprising the steps of fixation, processing, imbedding, deparaffinization and dehydration, or applying ultrasound at a frequency of at least 100 kHz to a sample during an analysis such as immunohistochemistry, in situ hybridization, fluorescent in situ hybridization, a Southern hybridization, a Northern hybridization, a Western annealing, or an ELISA, as recited in claim 38. Lanza is concerned with ultrasonic imaging, drug or chemotherapeutic agent delivery, and diagnostic assays and detection systems, as described at column 1, lines 16-18, not applying ultrasound at a frequency of at least 100 kHz during each step except imbedding while preparing a sample for analysis comprising the steps of fixation, processing, imbedding, deparaffinization and dehydration, or applying ultrasound at a frequency of at least 100 kHz to a sample during an analysis such as immunohistochemistry, in situ hybridization, fluorescent in situ hybridization, a Southern hybridization, a Northern hybridization, a Western annealing, or an ELISA, as recited in claim 38.

Finally, Lanza's goal is adapting ligand-based binding systems to an ultrasonic contrast system, as described at column 2, lines 31 and 32, not applying ultrasound at a frequency of at least 100 kHz during each step except imbedding while preparing a sample for analysis comprising the steps of fixation, processing, imbedding, deparaffinization and dehydration, or applying ultrasound at a frequency of at least 100 kHz to a sample during an analysis such as immunohistochemistry, in situ hybridization, fluorescent in situ hybridization, a Southern hybridization, a Northern hybridization, a Western annealing, or an ELISA, as recited in claim

38. Claim 38 is submitted to be allowable. Withdrawal of the rejection of claim 38 is earnestly solicited.

Claims 39, 40, 43, 45 through 48, 56, and 58, 61, 63, and 64 depend from claim 38 and add further distinguishing elements. Claims 39, 40, 43, 45 through 48, 56, and 58, 61, 63, and 64 are also submitted to be allowable. Withdrawal of the rejection of claims 39, 40, 43, 45 through 48, 56, and 58, 61, 63, and 64 is earnestly solicited.

Claim Rejections - 35 U.S.C. § 103:

Claims 38-42, 45, 48, 58, 61, and 69 were rejected under 35 U.S.C. § 103 as being unpatentable over Chen et al., "Ultrasound Accelerated Immunoassay, as Exemplified by Enzyme Immunoassay of Choriogonadotrpin," 1984, Clinical Chemistry, 30(9), 1446-1451 in view of Lee, U.S. 6,086,821. The rejection is traversed, to the extent it might apply to the claims as amended.

Neither Chen nor Lee describe either applying ultrasound at a frequency of at least 100 kHz during each step except imbedding while preparing a sample for analysis comprising the steps of fixation, processing, imbedding, deparaffinization, and dehydration, or applying ultrasound at a frequency of at least 100 kHz to a sample during an analysis such as immunohistochemistry, in situ hybridization, fluorescent in situ hybridization, a Southern hybridization, a Northern hybridization, a Western annealing, or an ELISA, as recited in claim 38. Since neither Chen nor Lee describe applying ultrasound at a frequency of at least 100 kHz during each step except imbedding while preparing a sample for analysis comprising the steps of fixation, processing, imbedding, deparaffinization, and dehydration separately, or applying ultrasound at a frequency of at least 100 kHz to a sample during an analysis such as immunohistochemistry, in situ hybridization, fluorescent in situ hybridization, a Southern hybridization, a Northern hybridization, a Western annealing, or an ELISA, their combination cannot, either.

Furthermore, Lee only warns about the forces due to cavitation with respect to the "method of the present invention", as described at column 13, lines 49-51. The method of the present invention, for Lee, is to only characterize the binding interactions in assays, as described at column 1, lines 9 and 10, as well as at column 4, lines 17, 22, 26, and 31. Lee says nothing one way or another about applying ultrasound at a frequency of at least 100 kHz

during each step except imbedding while preparing a sample for analysis comprising the steps of fixation, processing, imbedding, deparaffinization, and dehydration. It would not have been obvious at the time of the invention therefore, for persons of ordinary skill in the art to modify Chen as proposed in the Office action, since Lee says nothing about how ultrasound may affect an immunoassay. Claim 38 is submitted to be allowable. Withdrawal of the rejection of claim 38 is earnestly solicited.

Claims 39-42, 45, 48, 58, 61, and 69 depend from claim 38 and add further distinguishing elements. Claims 39-42, 45, 48, 58, 61, and 69 are also submitted to be allowable. Withdrawal of the rejection of claims 39-42, 45, 48, 58, 61, and 69 is earnestly solicited.

Claims 41, 42, 44, 46, 47, 48, 49, 51, 53, 54, 55, 57, and 69 were rejected under 35 U.S.C. § 103 as being unpatentable over various combinations of Lanza and Gravlee, Jr. US 3,961,097, Blank et al., US 5,913,826, Lang et al., US 5,941,825 and Kretz, US 4,403,509. The rejection is traversed, to the extent it might apply to the claims as amended.

Claims 41, 42, 44, 46, 47, 48, 49, 51, 53, 54, 55, 57, and 69 depend from claim 38 and add further distinguishing elements. None of the cited references describe either applying ultrasound at a frequency of at least 100 kHz during each step except imbedding while preparing a sample for analysis comprising the steps of fixation, processing, imbedding, deparaffinization, and dehydration, or applying ultrasound at a frequency of at least 100 kHz to a sample during an analysis such as immunohistochemistry, in situ hybridization, fluorescent in situ hybridization, a Southern hybridization, a Northern hybridization, a Western annealing, or an ELISA, as recited in claim 38. Since none of the cited references describe either applying ultrasound at a frequency of at least 100 kHz during each step except imbedding while preparing a sample for analysis comprising the steps of fixation, processing, imbedding, deparaffinization, and dehydration, or applying ultrasound at a frequency of at least 100 kHz to a sample during an analysis such as immunohistochemistry, in situ hybridization, fluorescent in situ hybridization, a Southern hybridization, a Northern hybridization, a Western annealing, or an ELISA separately, their combination cannot, either.

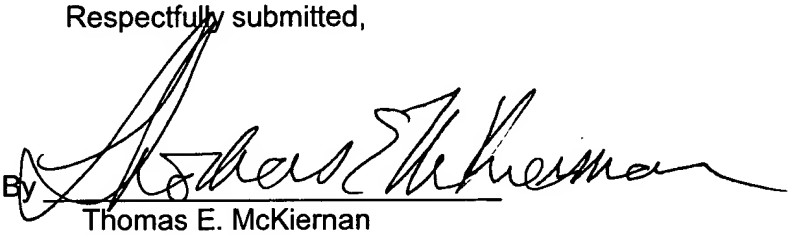
With respect to the combination of Lanza and Gravlee, even if it were obvious to discover the optimum workable range of the methods disclosed by Lanza, as asserted in the

Office action at page 6, there is still no basis for a conclusion that it would be obvious to discover the optimum workable range of a method of applying ultrasound at a frequency of at least 100 kHz during each step except imbedding while preparing a sample for analysis comprising the steps of fixation, processing, imbedding, deparaffinization, and dehydration, or applying ultrasound at a frequency of at least 100 kHz to a sample during an analysis such as immunohistochemistry, in situ hybridization, fluorescent in situ hybridization, a Southern hybridization, a Northern hybridization, a Western annealing, or an ELISA, as recited in claim 38. Claims 41, 42, 44, 46, 47, 48, 49, 51, 53, 54, 55, 57, and 69 are also submitted to be allowable. Withdrawal of the rejection of claims 41, 42, 44, 46, 47, 48, 49, 51, 53, 54, 55, 57, and 69 is earnestly solicited.

Conclusion:

Accordingly, in view of the reasons given above, it is submitted that all claims 38 through 58, 61, 64, 65, 66, 68, and 69 are allowable over the cited references. Allowance of all claims 38 through 58, 61, 64, 65, 66, 68, and 69 and of this entire application are therefore respectfully requested.

Respectfully submitted,

By 

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